Kinesis Health Technologies

Kinesis QTUG™
Mobility and Falls Risk Assessment Technology
Evidence Base

Introduction

Kinesis QTUG™ is an evidence-based technology for the assessment of falls risk, frailty and mobility. Based on the standard Timed Up and Go test, QTUG™ employs body-worn sensors and machine learning algorithms and is based on 13 years of peer reviewed research.

Our technology uses advanced wearable sensors suitable for the objective assessment of gait and mobility, measurement of response to an intervention and for screening for falls risk, mobility impairment and frailty.

It is intended for use by a health or care worker in assessing the mobility and falls risk of an older adult. QTUG™ uses body-worn inertial sensors along with questionnaire data to objectively assess movement. It produces a validated falls risk score (known as the falls risk estimate) as well as a frailty score (known as the frailty estimate). In addition, it tracks clinical risk factors, provides a detailed 71 parameter gait and mobility assessment which provides an indication of the source of falls risk (through comparison against a large reference data set) as well as advice on interventions to prevent falls.

Regulatory

QTUG™ is a Class I medical device, registered under the Medical Device Regulations (MDR 2017/745), notified body: Health Products Regulatory Authority (HPRA, Ireland. Kinesis are also registered as Class I medical devices in the USA, Canada, Australia, South Korea, Singapore, Thailand and Malaysia. Kinesis products are compliant with the EU General Data Protection Rules (GDPR) for storage of personal information and with the US HIPAA privacy laws.

Economic evidence

To assess cost-effectiveness, an exploratory economic model was developed by School of Health and Related Research (ScHARR) at the University of Sheffield[21]. According to this model screening with QTUG™ produces more Quality Adjusted Life Years (QALYs) and cost-savings than paper-based assessments and if falls-risk screening was sought by clinicians, QTUG™ should be considered rather than the manual Timed Up & Go test for people aged 75 to 89.

QTUG™ Features:

- Validated statistical prediction of Falls Risk and Frailty.
- Precise measurement of patient's performance both pre and post rehabilitation or intervention.
- Comprehensive mobility assessment based on the Timed Up & Go test compared against a large reference data set.
- Colour-coded comparison of patient to population across 71 parameters.

- Portable solution that is suitable for use in home and in the community.
- Real-time reporting; generates detailed results at the point and time of assessment.
- Ability to integrate with 3rd party Electronic Health Record (EHR) systems.
- Tracks assessor and assessments locations for audit purposes.
- Usability – quick and easy to use; can be administered by a broad range of health/care workers.
- Cloud data hosting and online portal for additional data analysis, audit and reporting.

Evidence

Kinesis products have been shown to be ***Valid***, ***Reliable*** and ***Accurate*** in measuring Gait and Mobility, as well as assessing Falls and frailty in older adults.

The following is a brief summary of the evidence supporting the product:

- QTUG produces more Quality Adjusted Life Years (QALYs) and cost-savings than paper-based assessments and if falls-risk screening was sought by clinicians. Results also suggested that a falls prevention care pathway had a higher probability of being cost-effective when screening and falls prevention interventions were utilised in a population aged 75 to 89[21].

- A study of 8,521 participants assessed using Kinesis QTUG™[14], examined gait, mobility and falls risk in 38 organizations in 6 countries over a 5 year period. We found that more than one fifth of older adults who have never reported a fall were at high risk and would perhaps stand to benefit most from an intervention. Similarly, by comparing against a large reference data set, some form of gait impairment was noted in almost 1 out of 5 of participants. One in four patients were predicted to be at high risk of falls with a similar proportion reporting a fall in the past 12 months.

- QTUG™ has been validated both prospectively (N=226) and cross-sectionally (N=748), and has been shown to provide an accurate measure of falls risk in older adults[5, 7, 9, 12, 15].
- In a comparison against standard measures (the time to complete TUG test and the Berg balance scale), QTUG™ has been shown to be significantly more accurate in assessing risk of falls[12, 15].

- Mobility parameters derived using Kinesis QTUG™ have been shown to provide reliable measurement of gait and mobility in: patients with multiple sclerosis (MS)[8], Parkinson's disease (PD)[10], older adults[24] and healthy controls[17].

- A study of 399 older adults showed that QTUG™ provides a robust and reliable estimate of patient's frailty state[11] as defined using the Fried frailty phenotype[2].

- A study of 38 MS patients and 33 controls showed that that mobility parameters derived from MS patients while completing the TUG test are reliable, are associated with disease state in MS and may have utility in screening for early stage MS[8]. QTUG has also been shown to be a more sensitive measure than UPDRS Part III for assessing the effect of exercise intervention on functional mobility in people with early-to-moderate stage PD[20].
- A longitudinal study of patients with Parkinson's disease (PD) found that QTUG™ predicts falls in PD within 3 months of assessment[10]. In addition, results showed that mobility parameters obtained using QTUG showed excellent inter-session reliability for assessment of patients with PD. QTUG has also been used to examine the effect of Deep Brain Stimulation (DBS) on mobility and falls risk in persons with PD[25].
- The inertial sensor algorithms contained in Kinesis QTUG™ have been validated against gold standards (optical motion capture system[6], forceplate[6] and GAITRite[3]) for assessment of temporal and spatial gait parameters in normal and pathological gait as well as treadmill running[18].
- Mobility parameters derived using Kinesis QTUG™ have been shown to be strongly linked to Minimum Ground Clearance (MGC)[19], which is strongly linked to risk of falls in older adults[13].
- A longitudinal study of 189 older adults showed that the change in mobility parameters obtained using QTUG™ measured two years after baseline assessment are associated with cognitive decline in older adults[4].
- A study of 119 older adults showed that changes in QTUG parameters were strongly associated with decline in balance as measured using the Berg Balance Scale (BBS)[22].
- A study of 16 participants examined the use of QTUG in assessing recovery in patients post hip fracture. QTUG was found to be a sensitive measure for assessing changes in functional mobility between admission and discharge for hip fracture patients. QTUG may also be useful for assessing falls risk and frailty at discharge post hip fracture surgery[1].
- QTUG™ has been successfully used to measure change in physical function and the response to intervention in both community dwelling older adults[23] and people with Parkinson's Disease[20].
- A study of 1057 participants, including 71 previously diagnosed with Parkinson's Disease (PD)[16], found that QTUG data can predict fall counts in PD and that falls counts predicted from the inertial sensor data obtained during a simple walking task have the potential to be developed as a novel digital biomarker for PD.

Contact

Contact us at sales@kinesis.ie for more information on how Kinesis Health Technologies can help improve care, reduce costs and prevent falls.

References

- 1 Grace Coakley, and Dara Meldrum, 'Quantitative Timed up and Go to Measure Falls Risk and Frailty Levels in Elderly Patients Post Hip Fracture', *Age and Ageing,* 45 (2016), ii13–ii56.
- 2 Linda P. Fried, Catherine M. Tangen, Jeremy Walston, Anne B. Newman, Calvin Hirsch, John Gottdiener, Teresa Seeman, Russell Tracy, Willem J. Kop, Gregory Burke, and Mary Ann McBurnie, 'Frailty in Older Adults: Evidence for a Phenotype', *J Gerontol A Biol Sci Med Sci,* 56 (2001), M146-57.
- 3 B. R. Greene, T. Foran, D. McGrath, E.P. Doheny, and A. Burns, 'A Comparison of Algorithms for Body-Worn Sensor Based Spatio-Temporal Gait Parameters to Gaitrite Electronic Walkway', *J. Applied Biomech.,* 28 (2012), 349-55.
- 4 B. R. Greene, and R. A. Kenny, 'Assessment of Cognitive Decline through Quantitative Analysis of the Timed up and Go Test', *IEEE Trans. Biomed. Eng.,* 59 (2012), 988-95.
- 5 B. R. Greene, D. McGrath, and B. Caulfield, 'A Comparison of Cross-Sectional and Prospective Algorithms for Falls Risk Assessment', *IEEE Engineering in Medicine & Biology Conference* (2014), 4527-30.
- 6 B. R. Greene, D. McGrath, R. O'Neill, K.J. O'Donovan, A. Burns, and B. Caulfield, 'An Adaptive Gyroscope Based Algorithm for Temporal Gait Analysis', *Medical & Biological Engineering & Computing,* 48 (2010), 1251-60.
- 7 B. R. Greene, S. J. Redmond, and B. Caulfield, 'Fall Risk Assessment through Automatic Combination of Clinical Fall Risk Factors and Body-Worn Sensor Data', *IEEE Journal of Biomedical and Health Informatics,* 21 (2016), 1-1.
- 8 B. R. Greene, S. Rutledge, I. McGurgan, C. McGuigan, K. O'Connell, B. Caulfield, and N. Tubridy, 'Assessment and Classification of Early-Stage Multiple Sclerosis with Inertial Sensors: Comparison against Clinical Measures of Disease State', *Biomedical and Health Informatics, IEEE Journal of,* 19 (2015), 1356-61.
- 9 B.R. Greene, E.P. Doheny, R.A. Kenny, and B. Caulfield, 'Classification of Frailty and Falls History Using a Combination of Sensor-Based Mobility Assessments', *Physiol. Meas. ,* 35 (2014), 2053-66.
- 10 Barry R. Greene, Brian Caulfield, Dronacharya Lamichhane, William Bond, Jessica Svendsen, Connie Zurski, and Dyveke Pratt, 'Longitudinal Assessment of Falls in Parkinson's Disease Using Inertial Sensors and the Timed up and Go Test', *Rehabilitation and Applied Technology Engineering (RATE),* 5 (2018).
- 11 Barry R. Greene, Emer P. Doheny, Aisling O'Halloran, and Rose A. Kenny, 'Frailty Status Can Be Accurately Assessed Using Inertial Sensors and the Tug Test', *Age and Ageing,* 43 (2014), 406-11.
- 12 Barry R. Greene, Emer P. Doheny, Cathal Walsh, Clodagh Cunningham, Lisa Crosby, and Rose A. Kenny, 'Evaluation of Falls Risk in Community-Dwelling Older Adults Using Body-Worn Sensors ', *Gerontology,* 58 (2012), 472-80.
- 13 Barry R. Greene, Denise McGrath, Timothy G. Foran, Emer P. Doheny, and Brian C. Caulfield, 'Body-Worn Sensor Based Surrogates of Minimum Ground Clearance in Elderly Fallers and Controls', in *Engineering in Medicine and Biology Society (EMBC), 2011 Annual International Conference of the IEEE* (Boston, MA: 2011).
- 14 Barry R. Greene, Killian McManus, Stephen J. Redmond, Brian Caulfield, and Charlene C. Quinn, 'Digital Assessment of Falls Risk, Frailty, and Mobility Impairment Using Wearable Sensors', *npj Digital Medicine,* 2 (2019), 125.
- 15 Barry R. Greene, Alan O'Donovan, Roman Romero-Ortuno, Lisa Cogan, Cliodhna Ni Scanaill, and Rose A. Kenny, 'Quantitative Falls Risk Assessment Using the Timed up and Go Test', *IEEE Trans. Biomed. Eng.,* 57 (2010), 2918-26.
- 16 Barry R. Greene, Isabella Premoli, Killian McManus, Denise McGrath, and Brian Caulfield, 'Predicting Fall Counts Using Wearable Sensors: A Novel Digital Biomarker for Parkinson&Rsquo;S Disease', *Sensors,* 22 (2022), 54.
- 17 D. McGrath, B. R. Greene, E. P. Doheny, David J. McKeown, Giuseppe De Vito, and B. Caulfield, 'Reliability of Quantitative Tug Measures of Mobility for Use in Falls Risk Assessment', in *Engineering in Medicine and Biology Society,EMBC, 2011 Annual International Conference of the IEEE* (2011), pp. 466-69.
- 18 Denise McGrath, Barry R Greene, Karol J O'Donovan, and Brian Caulfield, 'Gyroscope-Based Assessment of Temporal Gait Parameters During Treadmill Walking and Running', *Sports Engineering* (2012), 1-7.
- 19 Denise McGrath, Barry R. Greene, Cathal Walsh, and Brian Caulfield, 'Estimation of Minimum Ground Clearance (Mgc) Using Body-Worn Inertial Sensors', *Journal of Biomechanics,* 44 (2011), 1083-88.

- 20 K. McManus, D. McGrath, B. R. Greene, O. Lennon, L. McMahon, and B. Caulfield, 'Impact of Exercise Intervention in Parkinson's Disease Can Be Quantified Using Inertial Sensor Data and Clinical Tests', in *2019 41st Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC)* (2019), pp. 3507-10.
- 21 S. Ariss, J. Read, M. Franklin, J. Dawson, N. Nasr, E. Scott, B. Field, K. Lowrie, H. Dunn, L. Cook, and R. Simmonds, 'Sheffield City Region Test Bed, 'Perfect Patient Pathway', (2018).
- 22 K. J. Sheehan, B. R. Greene, C. Cunningham, L. Crosby, and R. A. Kenny, 'Early Identification of Declining Balance in Higher Functioning Older Adults, an Inertial Sensor Based Method', *Gait & Posture,* 39 (2014), 1034-39.
- 23 Erin Smith, Caitriona Cunningham, Barry R. Greene, Ulrik McCarthy Persson, and Catherine Blake, 'Detecting Subtle Mobility Changes among Older Adults: The Quantitative Timed up and Go Test', *Aging Clinical and Experimental Research,* 33 (2021), 2157-64.
- 24 Erin Smith, Lorcan Walsh, Julie Doyle, Barry Greene, and Catherine Blake, 'The Reliability of the Quantitative Timed up and Go Test (Qtug) Measured over Five Consecutive Days under Single and Dual-Task Conditions in Community Dwelling Older Adults', *Gait & Posture,* 43 (2016), 239-44.
- 25 J. Somerset, B. Hammersley, and M. Bonello, 'Can the Quantified Timed up and Go (Qtug) Device Support Decision Making for Patients Undergoing Deep Brain Stimulation?', *Mov Disord.,* 34 (2019), suppl 2.